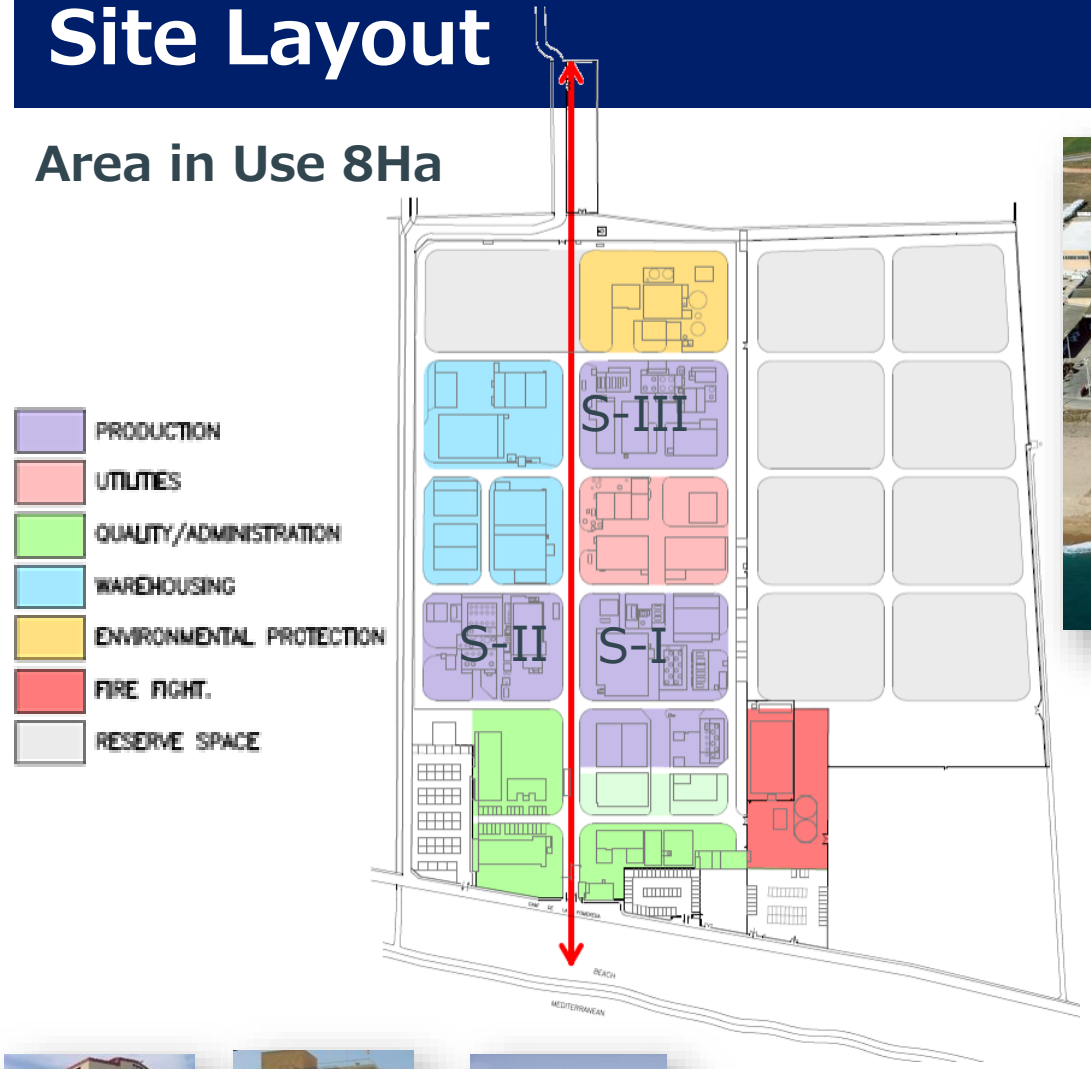
AGC Pharma Chemicals Europe, S.L.U.

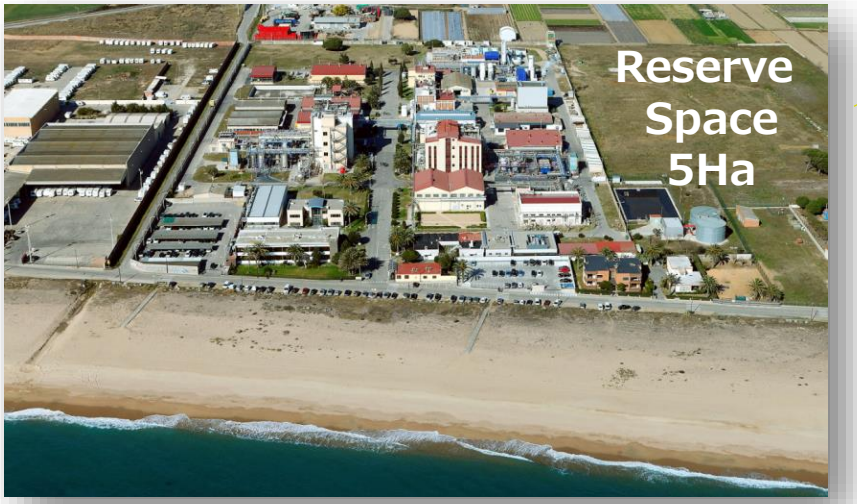
Your Dreams, Our Challenge

Vision - Mission

Site Layout

Area in Use 8Ha





24,000 m² in buildings/constructions

De-centralized S-I, S-II and S-III plants

Water wells and potabilization plant

Biological WWTP and seawater pipeline

Postcombustor (VOC's incineration)

Standard Control System **Siemens PCS7**

S-I

S-II

S-III

Three Synthesis Facilities and Pilot Plant

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- cGMP compliance
- Production capability is set up in a multipurpose concept for the production of small molecule
- The facilities provide 120 m³ of total reactor capacity with vessel sizes of up to 6 m³
- Process chemistry can be conducted at temperatures between -20ºC and +190ºC

New Investments – Press Release April 2020

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Expansion production capacity (May 2022) and new R&D facility (March 2021)

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News Release

AGC to Expand its Spanish Synthetic Pharmaceutical Production Base
Increase of Production Capacity and Establishment of a New R&D Facility

Tokyo, April 7, 2020–AGC Inc.(AGC), a world-leading manufacturer of glass, chemicals and high-tech materials, has announced its decision to expand facilities at its pharmaceuticals[*1] CDMO[*2] business subsidiary AGC Pharma Chemicals Europe S. L. U., headquartered in Spain.

This initiative will not only upgrade existing production facilities to achieve 1.3 times the capacity of the current production level, but also establish a brand-new R&D facility. The new R&D facility is scheduled to begin operation in March 2021, while the expanded facility is scheduled to begin in May 2022.

AGC Pharma Chemicals Europe exterior

Exterior of new research building

AGC Pharma Chemicals Europe, a synthetic pharmaceutical CDMO, was acquired from Boehringer Ingelheim in March 2019 in order to establish a synthetic pharmaceutical production capability in Europe, to supply active pharmaceutical ingredients and their intermediates. In October of the same year, the name was changed from Malgrat Pharma Chemicals to its current AGC Pharma Chemicals Europe. The company has a long history and wealth of experience in the manufacture of GMP[*3] compliant pharmaceutical ingredients, and is capable of handling a wide range of production from development drugs to commercial drugs.

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The synthetic pharmaceutical CDMO market is growing at over 7% annually, while the number of contracts handled by the company are growing at an even faster rate. To satisfy this accelerating demand, existing production facilities will be upgraded to increase pharmaceutical production capacity by 1.3 times that of the current level. A new micronization facility will also be introduced to respond to the increasing demand for micronization of active pharmaceutical ingredients. In addition, a brand-new R&D facility will be built which will enable development of processes from lab scale to commercial production, and to deliver better and faster services to customers.

Under its ***AGC plus*** management policy, the AGC Group has made a commitment to position life-sciences related business, including the pharmaceutical CDMO business, as one of its strategic initiatives, aiming at sales in the 100-billion-yen range by 2025. In addition to mergers and acquisition, AGC is actively investing in facilities in Japan, the US and Europe. AGC will continue to provide customers in each region with globally consistent, top-level quality and service in the life sciences sector, which is expected to exhibit significant growth in the coming years. By maximizing synergies among operation sites, AGC will enhance its technology and continue to pursue its goal of being a company that contributes to pharmaceutical companies, medical patients, and the society.

MEDIA INQUIRIES
Kazumi Tamaki, General Manager, Corporate Communications & Investor Relations Division
AGC Inc.
(Contact: Yuki Kitano; Tel: +81-3-3218-5603; E-mail: info-pr@agc.com)
*Handling of personal information is governed by our privacy policy.

AGC Pharma Chemicals Europe
Quality & EHS & Sustainability

Health Authority Inspections in the last years

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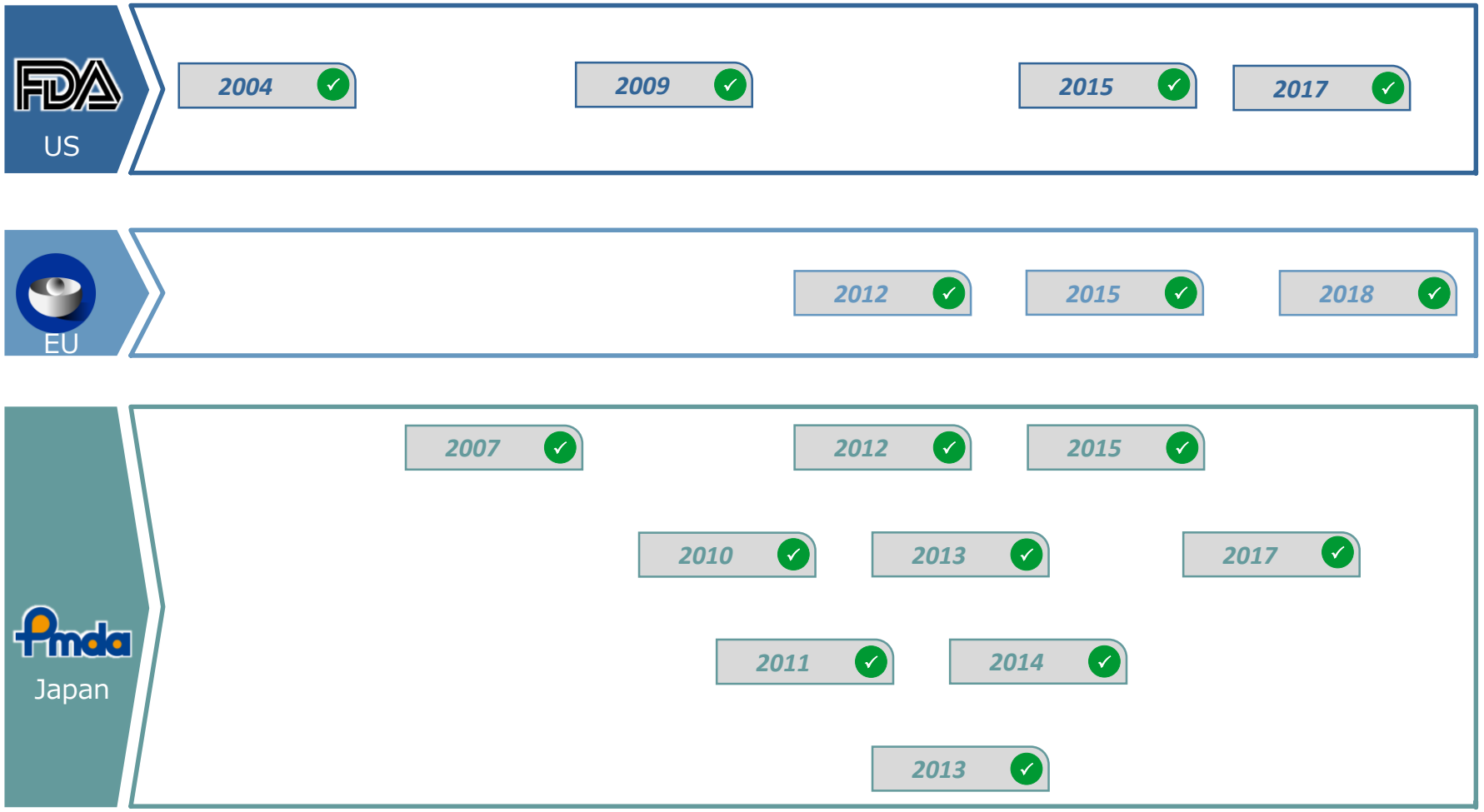
Flawless compliance track record
No 483 observations (FDA) / no critical/major findings (EMA & PMDA)



GMP Certification (EMA)

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Generalitat de Catalunya
Departament de Salut
Direcció General d'Ordenació i Regulació Sanitària

Certificat número
Certificado número
Certificate number **NCF-II/1934/001/CAT**

Certificat de compliment de les normes de correcta fabricació de medicaments (NCF) d'un fabricant

Part 1

Emès com a conseqüència d'una inspecció duta a terme d'acord amb l'article 111(5) de la Directiva 2001/83/EC.

L'autoritat competent de la Generalitat de Catalunya - España certifica que:

L'empresa, en la planta que s'indica a continuació:

Certificado de cumplimiento de las normas de correcta fabricación de medicamentos (NCF) de un fabricante

Parte 1

Emitido en virtud de una inspección según el artículo 111(5) de la Directiva 2001/83/CE.

La autoridad competente de la Generalitat de Catalunya - España certifica que:

La empresa, en la planta que se indica a continuación:

Certificate of Good Manufacturing Practices (GMP) compliance of a manufacturer

Part 1

Issued following an inspection in accordance with Article 111(5) of Directive 2001/83/EC.

The competent authority of the Government of Catalonia – Spain certifies that:

The manufacturer, in its site address indicated below:

AGC PHARMA CHEMICALS EUROPE, S.L.U.

Camí de la Pomereda, 13

08380 MALGRAT DE MAR (BARCELONA)

Es un fabricant de principis actius farmacèutics que ha estat inspeccionat d'acord amb l'article 111(1) de la Directiva 2001/83/EC, incorporada a la legislació nacional següent: articles 64 i 108 del Reial decret legislatiu 1/2015 i Reial decret 824/2010.

A partir de la informació obtinguda en les visites d'inspecció a aquesta empresa, l'última de les quals es va realitzar a:

maig 2018 (23, 24 i 25)

Es considera que compleix els requisits establerts a les Normes de Correcta Fabricació (NCF) per a principis actius farmacèutics a les quals es fa referència a l'article 47 de la Directiva 2001/83/CE.

Aquest certificat reflexa la situació de la planta de fabricació en la data en què es va fer la inspecció citada abans, i no pot considerar-se que acrediti el compliment si han transcorregut més de 4 anys des de la data de dita inspecció. Passat aquest temps, ha de consultar-se la validesa del certificat amb l'autoritat emissora.

Aquest certificat és vàlid solament si es presenta amb totes les pàgines i les dues parts, la 1 i la 2.

Es un fabricante de sustancias activas inspeccionado de acuerdo con el Art. 111(1) de la Directiva 2001/83/CE, incorporada en la siguiente legislación nacional: articulos 64 y 108 del Real decreto legislativo 1/2015 y Real decreto 824/2010.

En base a la información obtenida en las visitas de inspección a esta empresa, la última de ellas realizada en:

mayo 2018 (23, 24 y 25)

Se considera que cumple con los requisitos establecidos en las Normas de Correcta Fabricación para sustancias activas a las que se hace referencia en el artículo 47 de la Directiva 2001/83/CE.

Este certificado refleja la situación de la planta de fabricación en la fecha en que se efectúa la inspección antes citada, y no puede considerarse que acredite el cumplimiento si han transcurrido más de 4 años desde la fecha de dicha inspección. Pasado ese periodo, deberá consultarse con la autoridad emisora sobre la validez del certificado.

Este certificado es válido solo si se presenta con todas las páginas y las dos partes, la 1 y la 2.

Is an active substance manufacturer that has been inspected in accordance with article. 111(1) of Directive 2001/83/EC, transposed in the following national legislation: articles 64 and 108 of Royal legislative decree 1/2015 and Royal decree 824/2010.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on:

May 2018 (23, 24 and 25)

it is considered that it complies with the Good Manufacturing Practice requirements for active substances laid down in Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than 4 years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

Nom i signatura de la persona autoritzada del Departament de Salut de la Generalitat de Catalunya – Espanya

Nombre y firma de la persona autorizada del Departamento de Salud de la Generalitat de Catalunya - España

Name and signature of the authorised person of the Ministry of Health of Government of Catalonia - Spain

Generalitat de Catalunya
Departament de Salut
Direcció General d'Ordenació i Regulació Sanitària

Maria Sardà Raventós
Directora general d'Ordenació i Regulació Sanitària

Barcelona, 28/10/2019

Departament de Salut
Direcció General d'Ordenació i Regulació Sanitària
Travessera de les Corts, 131-159 (pavelló Ave Maria)
08028 Barcelona

Telf. 93 556 61 62
Fax. 93 227 29 90

EHS Compliance

- **Industrial Safety:**
  - Site under SEVESO Directive (lower tier)
- **Environment:**
  - Site under IPPC Directive (Integrated Pollution Prevention and Control)
- **Health and Safety:**
  - H&S Management Organization according to Spanish Prevention Law (Ley 31/1995)

Chemistry
for a Blue Planet
AGC Chemicals

Management System Certifications

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Environmental Management System

ISO 14001:2015

Health & Safety Management System:

OHSAS 18001:2007

On-going adaptation to ISO 45001

Certificate

Standard ISO 14001:2015

Certificate Registr. No. 3.00.08071

TÜV Rheinland Ibérica Inspection, Certification & Testing S.A. certifies:

Certificate Owner: MALGRAT PHARMA CHEMICALS, S.L.U.
Cami de la Pomereda, 13
08380 Malgrat de Mar (Barcelona)
Spain

Scope: Production of fine chemicals and active pharmaceutical ingredients.

An audit was performed, Report No. 3.00.08071 Proof has been furnished that the requirements according to ISO 14001:2015 are fulfilled.

The due date for all future audits is 12-12 (mm - dd).

Validity: The certificate is valid from 2018-02-02 until 2021-0
First certification 2009.

2018-01-19 TÜV Rheinland Ibérica Inspection, Certification
Garrotxa, 10-12 – E-08820 El Pr

www.tuv.com

IAF ENAC CERTIFICACIÓN

TÜVR
Precisely

Certificate

Standard BS OHSAS 18001:2007

Certificate Registr. No. 77 113 170040

TÜV Rheinland Ibérica Inspection, Certification & Testing S.A. certifies:

Certificate Owner: MALGRAT PHARMA CHEMICALS, S.L.U.
Cami de la Pomereda, 13
08380 Malgrat de Mar (Barcelona)
Spain

Scope: Production of fine chemicals and active pharmaceutical ingredients.

An audit was performed, Report No. 77 113 170040 Proof has been furnished that the requirements according to BS OHSAS 18001:2007 are fulfilled.

The due date for all future audits is 10-27 (mm - dd).

Validity: The certificate is valid from 2018-01-31 until 2021-01-27.
First certification 2018.

2018-02-07 TÜV Rheinland Ibérica Inspection, Certification & Testing S.A.
Garrotxa, 10-12 – E-08820 El Prat de Llobregat

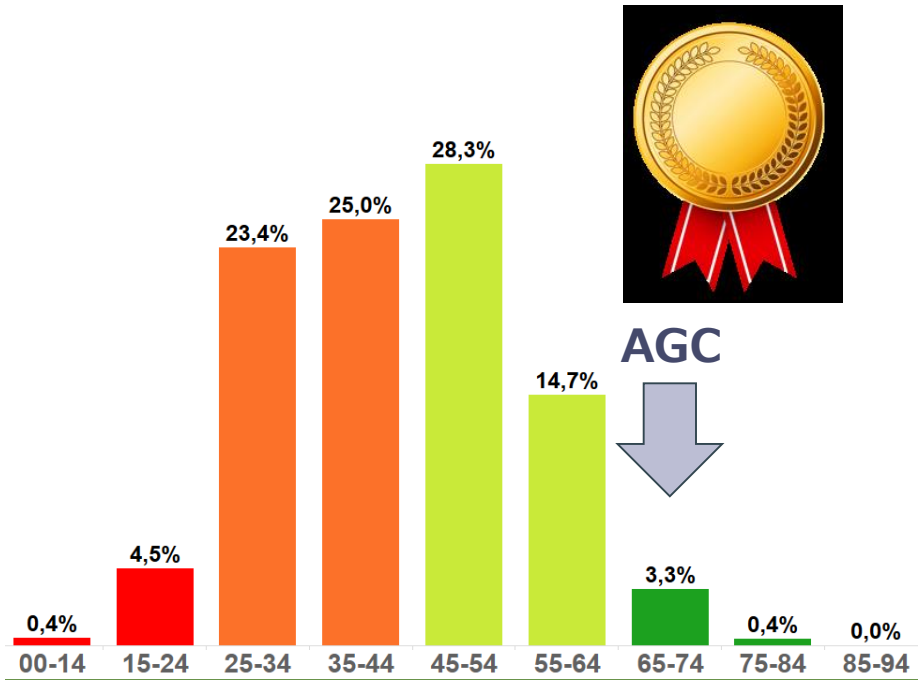
www.tuv.com

ENAC CERTIFICACIÓN

TÜVRheinland®
Precisely Right.

AGC commits to Sustainability
EcoVadis Assessment

AGC Pharma Chemicals Europe got “**Gold**” medal in June 2020



Accreditation for supplier’s sustainability performance

Responsible Care ®

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Malgrat de Mar Site participates since 1993 in **Responsible Care®,** an initiative of the international chemical industry

Since 2015, the site has be recognized by FEIQUE, the Spanish Chemical Association, as a “Responsible Care” Company

Security

Environmental Protection

Product Stewardship

Employees Health & Safety

RESPONSIBLE CARE
El Compromiso de la Industria Química con el Desarrollo Sostenible

Transport & Storage Safety

Process Safety & Emergency Preparedness

Responsible Company


Responsible Care CSR COMPANY

feiQue

RESPONSIBLE CARE

CERTIFICATE

The Spanish Chemical Industry Federation (FEIQUE), as representative and coordinator of the Global Responsible Care initiative in Spain,
Certifies that the company

MALGRAT PHARMA CHEMICALS

Meets the following requirements that grant recognition as a Responsible Care CSR Company

- The Company is committed to the Responsible Care initiative and to the continuous improvement of Safety, Health and Environmental Protection in all its operations according to the principles of Sustainable Development and Corporate Social Responsibility.
- Accomplish all the requirements to belong to the Responsible Care program, including the signature of its Responsible Care Global Charter (ICCA, 2014).
- The Indicators of Performance reporting and the Management Practices assessment of the Seven Codes included in the Responsible Care FEIQUE Program.
- Pass the annual verification scheme established by FEIQUE to assess compliance with the practices of the Codes of Management.
- Encourage the development of CSR policies promoted by FEIQUE and collaborates in promoting compliance with the objectives and spirit of the Responsible Care Program.

This certificate is valid from march 1, 2019 to march 1, 2021

And as evidence hereby, I sign this certificate in Madrid, on March 1, 2019.

Mr. Juan Antonio Labat Arangüena
FEIQUE Director General and Chairman of Responsible Care Spain Committee

AGC's Corporate Social Responsibility

AGC Pharma Chemicals Europe CSR activities

- Malgrat de Mar **Beach cleaning** after Gloria storm in Catalonia
- **International Day for free plastic bags**: APCE designed a reusable bag made of cloth

- **International day of women in Science**: APCE women gave a chemistry class in local school
- Donation of **masks for COVID-19 protection**
- **Laptops donation** to Malgrat Council

- Offering **value to customers**
- Ensuring **Fair Trade**
- Development of **Sustainable Business Operations**

- **International day of Women**: promotion of APCE female employees on LinkedIn
- **International day of Nutrition**: recommendation to employees on healthy way of life
- **Road safety campaign**

AGC Pharma Chemicals Winners of the Keicho Award November 2020 for outstanding activity in Spain.

AGC Pharma Chemicals CSR activities

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AT APCE WE ARE

Sustainable

YOU TOO?

PROTECT THE ENVIRONMENT
HELP THE DISADVANTAGED ONES

12 RESPONSIBLE CONSUMPTION AND PRODUCTION

With your help we support the Sustainable Developement Goals

1 NO POVERTY

AGC Pharma Chemicals Europe
Business Process Excellence

BPE based in Lean and Six Sigma

- **Embedded at all levels in the organization**

1x master black belt

8x black belt

19x green belt

28x yellow belt

253x white belt

AGC Pharma Chemicals Europe
The First choice CDMO

AGC's strengths

Assurance of Supply	• Financial healthy group • Technical Expertise • Business Continuity Planning
Quality	• Global Pharma Audits • Regulatory Authority Audits
Service/ Sustainability	• European production plant with free capacity • On Time In Full (OTIF)/Right First Time (RFT) • EHS (Gold Recognition from EcoVadis)
Cost	• Competitive cost • Owner of unique raw material, in-house F-chemicals
Innovation	• Production scale fluorination. • Process improvement

END

AGC

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